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Notice of Allowability	Application No.	Applicant(s)	
	10/040,964	MANFREDI ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 3 February 2004.
2. ☒ The allowed claim(s) is/are 65-92.
3. ☒ The drawings filed on 4 January 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
|---|--|

EXAMINER'S AMENDMENT

It is noted that claims 65 and 66 are not patentably distinct over claims 1 and 2 of copending Application No. 10/040,969 (henceforth the '969 application), because the claims from the '969 application are species claims that necessarily anticipate the genus claims of the instant application. However, because this would represent a provisional obviousness-type double patenting rejection, and would be the only outstanding rejection in the instant application, the rejection is obviated as per MPEP § 822.01.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Andrew Gibbs on April 2004.

Please amend the specification as follows:

Please disable the hyperlink on page 13.

Please amend the claims as follows:

67. The method of Claim 66, wherein at least one of said first or second fusion proteins further contain an amino acid sequence capable of enabling at least one of the expressed first or second fusion proteins to exhibit sufficient affinity to a cell surface protein or cell membrane component

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to effect binding of the molecule to the surface of the cell membrane or to at least partially anchor to the cell membrane of the host cell.

72. The method of Claim 67, wherein one of said first or second test polypeptides ~~is at least partially anchored to the cell membrane~~ exhibits sufficient affinity to a cell surface protein or cell membrane component to effect binding of the molecule to the surface of the cell membrane or anchors to the cell membrane, while the other is contained inside the cell.

73. The method of Claim 67, wherein both of said first and second test polypeptides exhibit sufficient affinity to a cell surface protein or cell membrane component to effect binding of the molecule to the surface of the cell membrane or anchor ~~are at least partially anchored to the cell membrane.~~

74. The method of Claim 67, wherein both of said first and second fusion proteins further contain an amino acid sequence capable of enabling both of the expressed first and second fusion proteins to exhibit sufficient affinity to a cell surface protein or cell membrane component to effect binding of the molecule to the surface of the cell membrane or to at least partially anchor to the cell membrane of the host cell, wherein said first and second test polypeptides at least partially reside outside the cell.

75. The method of Claim 67, wherein both of said first and second fusion proteins further contain an amino acid sequence capable of enabling both of the expressed first and second fusion

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proteins to exhibit sufficient affinity to a cell surface protein or cell membrane component to effect binding of the molecule to the surface of the cell membrane or to at least partially anchor to the cell membrane of the host cell such that said first and second test polypeptides are exposed outside the cell while the inactive reporter polypeptides and the N-intein and C-intein are retained within the cell.

92. The kit of Claim 90, wherein at least one of said first and second chimeric genes further contains a nucleotide sequence encoding an amino acid sequence capable of enabling at least one of the expressed first or second fusion proteins to exhibit sufficient affinity to a cell surface protein or cell membrane component to effect binding of the molecule to the surface of the cell membrane or to at least partially anchor to the cell membrane of the host cell.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
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JAMES KETTER
PRIMARY EXAMINER